Zedler, Barbara

From: Sarkar, Mohamadi
Sent: Friday, June 27, 2003 8:12 AM
To: Unverdorben, Martin; Adams, Candace R.; Barbara Zedler; Feng, Shixia; Gogova, Maria; Jin, Yan; King, Valerie A.; Kinser, Robin D.; Liang, Qiwei; Mawyer, Denise T.; Mendes, Paul; Nelson, Bettie L; Oey, Jan; Roethig, Hans
Subject: Roche Gene Test Promises To Tailor Drugs to Patients (from FDA clips): CYP450 polymorphisms are important after all

FYI - CYP450 genetic polymorphisms are becoming more and more relevant.

Sincerely,

Mohamadi Sarkar

From: "Jadhav, Pravin *" <JadhavP@cder.fda.gov>
Date: Thu, 26 Jun 2003 10:39:46 -0400

> June 25, 2003
> Roche Gene Test Promises
> To Tailor Drugs to Patients
> Precise Genetic Approach Could Mean
> Big Changes in Development, Treatment
> By VANESSA FUHRMANS
> Staff Reporter of THE WALL STREET JOURNAL
> Roche Holding AG is launching the first gene test able to predict how a
> person will react to a large range of commonly prescribed medicines, one
> of the biggest forays yet into tailoring drugs to a patient's genetic
> makeup.
> The test is part of an emerging approach to treatment that health experts
> expect could lead to big changes in the way drugs are developed, marketed
> and prescribed. For all of the advances in medicine, doctors today
> determine the best medicine and dose for an ailing patient largely by
> trial and error. The fast-growing field of "personalized" medicine hopes
> to remove such risks and alter the pharmaceutical industry's more
> one-size-fits-all approach in making and selling drugs. Roche
> initially will make the test available to about 400 specially
> certified U.S. laboratories, most of which are connected to large
> hospitals or other medical centers. Any doctor can ask for a test before
> writing a prescription, but would have to get in touch with one of the
> designated laboratories to have it done. By late 2004, Roche hopes to have
> approval from the U.S. Food and Drug Administration to sell it more widely
> as a diagnostic test.
> Each test will cost the laboratories $350 to $400 to perform. Roche
> predicts its sales will reach $100 million annually by 2008. This is
> relatively low for a new pharmaceuticals company product, indicating Roche
> expects personalized drug treatment will take some time to gain widespread
> usage.

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> One day, as researchers envision it, doctors will first scan a sample of a
> patient's DNA, then custom-fit a drug regimen to his or her genetic
> profile. Some genetic tests already are used for certain diseases and
> treatments. Oncologists, for instance, routinely use a blood test that can
> identify the 10% of childhood-leukemia patients who experience dangerous
> side effects to a key treatment.
> The Roche test, called the AmpliChip CYP450, is the first of its kind to
> check how well a patient will respond to a number of drug types, from
> antidepressants to blood-pressure pills to codeine. With a drop of blood
> or a smear from the inside of a patient's cheek, the gene chip checks for
> dozens of variations in two genes known to play a critical role in
> metabolizing a quarter of the prescription drugs on the market.
> Researchers have known for years that the genes, called CYP2D6 and
> CYP2C19, figure largely in how people break down many drugs. Because of
> certain mutations or differences in one or both of the genes, some people
> metabolize certain drugs poorly, meaning that they have trouble
> inactivating and eliminating them from the body. Poor metabolizers, who
> make up between 3% and 10% of the general population, have a higher risk
> of experiencing an adverse reaction to a drug. Other people have
> additional copies of the genes and therefore metabolize drugs excessively.
> This usually causes them to eliminate the drug before it has had a chance
> to work.
> In the U.S. alone, roughly two million hospital patients a year suffer
> from an adverse drug reaction, of which 100,000 die. Researchers believe
> as many as 10% to 20% of those cases could be avoided with the right
> gene-based diagnostic tools. Such tests also could give patients a
> critical head start on the best treatment against life-threatening
> diseases. Roche says the test, which is run on a gene chip developed
> by Affymetrix
> Inc., Santa Clara, Calif., is capable so far of determining how well a
> patient is likely to metabolize certain classes of drugs. "Having that
> [information], clinicians can decide how to adjust the dose," said Walter
> Koch, director of pharmacogenetics at Roche's molecular diagnostics
> division. For more specific results that can pinpoint the optimal dose
> of a certain
> drug, more studies are needed, he adds. One of the first areas the Swiss
> drug maker is exploring is antidepressants, which patients often spend
> weeks, even months, cycling through before finding a regimen that works or
> doesn't trigger miserable side effects.
> Roche's test would begin with the doctor drawing a sample of blood or
> swabbing the inside of a patient's cheek, then sending it to a lab. There,

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> lab researchers would carry out a Roche-patented process called polymerase
> chain reaction, which can extract and replicate tiny amounts of the
> specific genes in question. Once enough is copied, it is placed on a
> thumbnail-size gene chip capable of identifying multitudes of variations
> or mutations. Results are back within eight hours, Roche executives say.
> The AmpliChip is the first product to come out of a $70 million
> partnership Roche struck with Affymetrix in January to use its gene-chip
> technology to develop diagnostic tests. The companies had begun working on
> the project. In addition to the AmpliChip CYP450, Roche is developing
> similar tests to screen for resistance to AIDS drugs, a patient's risk of
> colorectal cancer and other diagnostic tools.
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